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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,678	04/26/2005	Masahiro Ishikawa	2005_0715A	4376

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EXAMINER	
TSAY, MARSHA M	

ART UNIT	PAPER NUMBER
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,678	ISHIKAWA ET AL.	
	Examiner	Art Unit	
	Marsha M. Tsay	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 26, 2009 has been entered.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Claims 1-8 are pending and currently under examination.

Priority: The request for priority to JAPAN 2002-328243, filed November 12, 2002, is acknowledged.

Objections and Rejections

Claim 1 is objected to because of the following informalities: in claim 1, line 2, the phrase "under acidic conditions" is redundant because the fractionation is done at a pH range of 4.5-5.6, which is inherently acidic. Appropriate correction is required.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6 and 8 are rejected under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter.

Claims 6 and 8, as written, do not sufficiently distinguish over 7S globulin and 11S globulins that exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, i.e. by insertion of "isolated" or "purified". See MPEP 2105.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 5, 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites acidic conditions of pH 3.8 to 6.8. Claim 3 is dependent on claim 1 which recites acidic conditions of pH 4.5 to 5.6. Therefore, the pH range of claim 3 is outside the range of claim 1. Claim 3 needs to be written independently or else the pH range needs to be corrected.

Claims 5 and 7 recite "the solid content." It is unclear what is meant by "the solid content" or what it is. Further, there is insufficient antecedent basis for this limitation in the claims or its parent claim. In the last line of claims 5 and 7, it is unclear what is being referred to, i.e. the lipid extract of the 7S globulin or just the lipid content in the 7S globulin. Further in

claims 5 and 7, line 3, the phrase "of said 7S globulin protein" or "of said 11S globulin protein", respectively, does not add any additional information to the claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 6, 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Saitoh et al. (US 6638562; previously cited). Saitoh et al. teach a 7S and an 11S globulin protein with a phytic content of 0.05% weight of protein (col. 9 line 18, lines 30-35). Claims 6, 8 are drawn to products, i.e. 7S globulin protein and 11S globulin protein whose phytic acid content is 1.2% by weight or less. Therefore, despite the process performed to obtain said globulin proteins, Saitoh et al. still teach 7S and 11S globulin proteins with a phytic content of 0.05% weight of protein, which is below the instantly claimed value of 1.2% by weight.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saitoh et al. (US 6638562; previously cited) in view of Ishikawa et al. (US 20050175766). Claim 1 has been given its broadest and most reasonable interpretation, i.e. a process for producing soybean protein comprising heating a soybean protein solution under acidic conditions, and then fractionating it (ionic strength 0.02-0.2, pH 4.5-5.6) into a soluble fraction and an insoluble fraction. In Example 2, Saitoh et al. disclose a process for producing soybean protein comprising heating a solution of defatted-soybean milk at pH 5.9 to 40°C (col. 9 lines 10-14). Saitoh et al. further disclose that phytase was added to the soybean protein solution and fractionated to obtain an insoluble fraction and a soluble fraction (col. 9 lines 16-20). Saitoh et al. disclose a 7S and an 11S globulin protein with a phytic content of 0.05% weight of protein (col. 9 line 18, lines 30-35). Saitoh et al. do not teach "fractionation conditions" at an ionic strength of 0.02 and pH of 4.5-5.6.

Ishikawa et al. disclose a method for obtaining 7S globulin which includes a heating step under acidic conditions (p. 2 [0019]) and then a separation step at an ionic strength less than 0.2 and at pH 4.0 to 5.0, followed by separation of an insoluble fraction (p. 2 [0024]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Saitoh et al. by using the fractionation conditions (ionic strength less than 0.2, pH 4.0 to 5.0) of Ishikawa et al. during the fractionation process of Saitoh et al. in order to obtain a soluble fraction and an insoluble fraction (claims 1-4). The motivation to do so is given by Ishikawa et al., which disclose that a pH range of 4.0-5.0 is the isoelectric point of 7S globulin and that at an ionic strength of less than 0.2, an insoluble fraction can be separated from a soybean protein solution containing 7S globulin.

While Ishikawa et al. do not teach a lower limit of 0.02 for the ionic strength, Ishikawa et al. still does disclose an upper limit of 0.2, as is also recited in claim 1. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990) (The prior art taught carbon monoxide concentrations of "about 1-5%" while the claim was limited to "more than 5%." The court held that "about 1-5%" allowed for concentrations slightly above 5% thus the ranges overlapped.) Also, generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be *prima facie* obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.")

Applicant's arguments, with respect to Nagano et al. have been fully considered and are persuasive. The rejection of claims 1-4, 6, 8 under 35 U.S.C. 103(a) as being unpatentable over

Saitoh et al. (US 6638562; previously cited) in view of Nagano et al. (JP 5043597; IDS 04.26.05) has been withdrawn.

However, upon further consideration of the claims and Applicants' amendment, the claims are still believed to be unpatentable over Saitoh et al. (US 6638562; previously cited) in view of Ishikawa et al. (US 20050175766; newly cited) for the reasons noted above.

Claims 5, 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saitoh et al. (US 6638562) in view of current knowledge of the art. The teachings of Saitoh et al. are outlined above. Saitoh et al. teach a ratio of 7S globulin/(11S globulin + 7S globulin) is 0.9 in the soluble fraction (col. 9 lines 30-40). Claims 5-7 recite a content of a polar lipid extracted by a mixed solvent of chloroform and methanol is 1% by weight or 2% by weight or less, respectively, which can include 0%; therefore, the instant process does not necessarily have to comprise the extraction step by a mixed chloroform and methanol solvent. Saitoh et al. do not teach a further fractionation step of the soluble fraction.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to further fractionate 7S globulin protein from the soluble fraction obtained by the fractionation process of Saitoh et al. (claim 5). The motivation to do so is provided by Saitoh et al. which discloses that the soluble fraction has a contamination rate of 2.9% of 11S globulin (col. 9 line 39); therefore, one of ordinary skill has a reasonable expectation of success in further fractionating the 7S globulin protein of Saitoh et al. because a further separation step will yield a purer 7S globulin protein product.

Saitoh et al. teach a ratio of 11S globulin/(11S globulin + 7S globulin) of 11S globulin protein is 0.9 in the insoluble fraction (col. 9 lines 30-40). Saitoh et al. do not teach a further fractionation step of the insoluble fraction.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to further fractionate 11S globulin protein from the insoluble fraction obtained by the fractionation process of Saitoh et al. (claim 7). The motivation to do so is provided by Saitoh et al. which discloses that the insoluble fraction has a contamination of 7.0% of 7S globulin (col. 9 line 39); therefore, one of ordinary skill has a reasonable expectation of success in further fractionating the 11S globulin protein of Saitoh et al. because a further separation step will yield a purer 11S globulin protein product.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

April 1, 2009